2-day training session for Clinical Pharmacologists

11am Thursday 29th – 4pm Friday 30th January 2015
RT-501-3, 151 Buckingham Palace Road

Draft programme

Day 1

10-11am	Registration and Refreshments
11am	**Welcome and Introduction** Overview of the work of MHRA
11.30am	**Clinical Trial applications** assessment of CTAs: how CTAs relate to ethics committee consideration; medical considerations; types of academic studies & common issues
12	**Inspections** GCP; GCP Inspections - what, why, when; common issues; Phase I unit accreditation; preventing over-volunteering; other GxP requirements: e.g. GPV inspections
12.30pm	**Pre-clinical information:** what is needed when for CTs; how this fits for licensing of medicines
1pm	*lunch* (c 1 - 2pm)
2 pm	**workshop**: e.g. review of CTA / CTA amendment
2.45pm	**Feedback from workshop**:
3.10pm	**Discussion / Q&As on Clinical trials**
3.20pm	*Tea/coffee*
3.40pm	**Licensing of medicines** Why do we license medicines? broad overview of data required; assessment process and Licence validity; committees / EU review;
4.10pm	**Quality matters:** need to ensure quality whether for an old or new product; implications for clinical usage
4.40pm	**Establishing efficacy - Statistical considerations in Clinical Trial Design: w**hat Regulators look for & how this may differ from academic statisticians
5.10pm	**Initial risk: benefit assessment - Clinical assessment of efficacy vs. safety:** surrogate vs. clinically relevant end points; indicated population; safety database: limitations & identifying issues; managing risk; extending indications
5.40pm	**Discussion / Q&As on licensing medicines**

6pm End of Day 1 – overnight reading of paper for workshop

Day 2

9.30 am	**workshop**: e.g. discussion of paper - regulatory vs. publication requirements
10.15 am	**Feedback from workshop**:
10.40	*Tea/coffee*
11 am	**Monitoring safety of medicines**: why, who & how
11.15 am	- **Triggers for safety concerns -** Yellow cards; how they work & how they contribute; what we need to know to assess the report;
11.30 am	- **Analysing safety data and investigating signals**: data mining, sources of data & types of studies (CPRD; PEM)
11.50 am	**- Assessing safety concerns** - comparing safety signals vs. the expected; strength of evidence; balancing risk v benefit
12.10 pm	- Bringing the data together: managing risk; EU co-ordination
12.30 pm	**Communicating changes in benefit/risk balance**
12.50 pm	**Discussion / Q&As on licensing medicines**
1 pm	*lunch* (c 1 – 2 pm)
2 pm	**workshop**: review of new safety information
2.45 pm	**Feedback from workshop**:
3.10 pm	**Medicines for paediatric patients:** key issues & how these are being addressed
3.30 pm	**Herbal Medicines or Devices?** key issues & future strategies
3.50 pm	**Career options**:

4pm End of Day 2